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Attorney General Beau Biden Announces Medicaid Fraud Settlement with Pharmaceutical Manufacturer Merck and Co.

Wilmington, DE - Delaware Attorney General Joseph R. Biden III announced today that the Delaware Medicaid Program will receive $960,380 and the state treasury will receive a $48,514 penalty as part of two related national settlements with Merck & Co., Inc. ("Merck"). The settlements – totaling $649 million – involve 49 states, the District of Columbia and the federal government.

"This is a significant recovery for Delaware taxpayers," Attorney General Biden said. "Any company that is considering defrauding Delaware taxpayers should know that we will hold them accountable to the fullest extent of the law. I pledge to the people of our state that the Delaware Department of Justice will continue to join with other states and the federal government in efforts to recover taxpayer dollars for Delawareans."

"Attorney General Biden has provided the Delaware Medicaid Fraud Control Unit with the resources it needs to combat sophisticated pharmaceutical fraud," stated prosecutor Daniel R. Miller, the Director of the Medicaid Fraud Control Unit (MFCU) in the Delaware Department of Justice. "Those resources permitted the Delaware Department of Justice to play a leading role in the investigation, prosecution, and settlement of these two cases."

The agreements with Merck resolve allegations that the company failed to pay rebates due to states' Medicaid Programs under the Federal Medicaid Drug Rebate statute (the "Best Price" statute). The settlements also resolve *qui tam* claims filed by whistleblowers in United States District Courts in Pennsylvania, Nevada, and Louisiana.

Federal law requires pharmaceutical manufacturers to give state Medicaid Programs the benefit of the lowest or "best" price available for their products. Manufacturers are required to regularly file "best price" information with the Centers for Medicare and Medicaid Services ("CMS"). This information is used to calculate rebates to be paid by manufacturers to the state Medicaid Programs. In general, lower "best prices" result in higher rebate obligations. In an exception to the statute, known as the "nominal price exception," extremely low prices which are "merely nominal" in amount (defined as 10% or less of the Average Manufacturer's Price ("AMP")) are exempt from the best price reporting requirement. The states have maintained that "merely nominal" means that the discounted price may not be tied to any conditions such as attainment of a certain market share or preferred formulary status.

The Pennsylvania and Nevada cases involve programs that featured agreement under which Merck would sell specific drugs to hospitals at a 92% discount from the catalog price, but only if the hospitals reached certain market share percentages for the drugs. The states contended that this market share condition violated the nominal price exception and thus rendered the discounts subject to best price reporting. The states further contended that Merck's failure to report these discounted prices to CMS as Merck's best price resulted in substantially lower rebates to the state Medicaid programs.

The Louisiana case involved Merck's sale of the drug Pepcid and another drug discount program. Under the Pepcid program, Merck sold the drug to hospitals in bundled pricing arrangements. In exchange for the hospital meeting a certain market share or other purchase requirement, Merck gave hospitals discounts of up to 92%. According to the government, the transactions under the discount drug program constituted "bundled sales" which required Merck to adjust "best price" among the different formulations to reflect these discounts. The states contended that Merck failed to reflect these discounts in their "best price" reports, resulting in less rebates paid to the state Medicaid Programs.

Delaware played a leading role in the investigation, prosecution, and settlement of these two cases. Going forward, the Delaware Department of Justice will continue to review alleged abuses of the nominal pricing exception, and any other alleged improper use of taxpayer money.

In addition to the monetary recovery announced today, Merck has entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services. The Agreement requires Merck to market, sell and promote its products in accordance with all Federal health care program requirements.

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